

## **REMARKS**

Claims 1, 4, 12-13, and 17, as amended, and claims 5-8, 9, 11, and 18-24 as filed are pending in the application. No new matter has been added as a result of the above-described amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

Although withdrawn from consideration pursuant to a Restriction Requirement, Applicants have not yet cancelled claims 9, 11 or 17-24 in compliance with MPEP §821.04.

The informalities objection regarding Claim 2 is rendered moot by Applicants' cancellation thereof

### **1. Election of Group I and Withdrawal of claim 3**

Applicant had previously elected Group I claims without traverse. The Office Action states that previously presented claim 3 was withdrawn from consideration as being directed to an invention that is independent or distinct from the invention originally claimed, but was incorrectly included in Group I. Applicant has accordingly withdrawn Claim 3.

### **2. Rejection of claims 1-2, 5-8, and 12-13 under 35 U.S.C. § 112, first paragraph**

The Office Action rejects claims 1-2, 5-8, and 12-13 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, because the claims are drawn to a genus of nucleic acids encoding a human hiwi gene and allelic variants of hiwi. The Examiner asserts that the claims contain subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Although Applicants respectfully disagree with the Examiner's interpretation of the claims, they have amended claim 1 to recite that the nucleic acids encompassed by the claim encode the amino acid sequence identified by SEQ ID No. 2, which is explicitly recited in the application. Applicants thus respectfully contend that the metes and bounds of their claims have been now unambiguously recited, and respectfully request that the Examiner withdraw this ground of rejection.

Regarding claims 12 and 13, also rejected on written description grounds, the U.S. Patent and Trademark Office Written Description Guidelines (issued January 5, 2001) explicitly state that a

nucleic acid is adequately described by a recitation of highly stringent hybridization conditions in combination with the disclosure of a nucleic acid encoding a particular gene, and that those with skill in the art would recognize that an applicant was in possession of the claimed invention based on this disclosure. When there is a single species disclosed that is within the scope of the claimed genus, and there is actual reduction to practice of the disclosed species, a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield *structurally* similar DNAs. Thus, a representative number of species is disclosed, due to the expected structural similarity of nucleic acid species isolated by high stringency hybridization.

Pending claims 12 and 13 recite high stringency hybridization and washing conditions using an explicitly-disclosed nucleic acid identified by SEQ ID NO: 1. The specificity with which Applicants have disclosed and claimed their invention fulfill the requirements of 35 U.S.C. §112, first paragraph, and Applicants thus request that the Examiner withdraw this ground of rejection.

**3. Rejection of claims 1-2, 4, and 12-13 under 35 U.S.C. § 101**

Claims 1-2, 4-8, and 12-13 stand rejected as being directed to non-statutory subject matter, for reciting nucleic acids that are products of nature. The Examiner has kindly suggested remedial amendments to the claims to overcome this ground of rejection. Accordingly, Applicants have amended claims 1-2, 4, and 12-13 pursuant to these helpful suggestions. Applicants thank the Examiner and respectfully requests the objection be withdrawn.

**4. Rejection of claims 1-2, 4, and 12-13 under 35 U.S.C. § 102**

The Office Action asserts that claims 1-2, 4-8, and 12-13 are anticipated under 35 U.S.C. §102(a) by Sharma *et al.*, 2001, "Human CD34+ stem cells express the *hiwi* gene, a human homologue of the *Drosophila* gene *piwi*." Blood 97: 426-434. Applicants submit herewith in unsigned copy a declaration from the named inventors pursuant to 37 C.F.R. §1.132, and respectfully submits that the claims are therefore not anticipated under § 102(a) by Sharma *et al.* A copy of Sharma *et al.* is enclosed with this response. A signed copy of this declaration shall be submitted to the Patent Office as soon as it comes to hand.

The Office Action also asserts that claims 1-2, 4-8, and 12-13 are anticipated under 35 U.S.C.

§ 102(b) by Lin (WO 00/32039). Amended claim 1 is now drawn to an isolated nucleic acid that encodes an amino acid sequence identified by SEQ ID NO: 2. This amino acid sequence is not identical to the sequence (identified by SEQ ID No. 6 in the Lin application) disclosed in the cited reference. In view of the differences between the claimed sequence and the Lin sequence, Applicants respectfully contend that the Lin reference does not anticipate the pending claims. Applicants therefore respectfully request the Examiner to withdraw rejection on 35 U.S.C. § 102(b) grounds.

### **CONCLUSIONS**

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner McKelvey believes it to be helpful, he is invited to contact the undersigned representative by telephone at (312) 913-0001.

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Respectfully submitted,  
**McDonnell Boehnen Hulbert & Berghoff**

By: 

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Kevin Noonan, Ph.D.  
Reg. No. 35,303